

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### The Effect of Virtual Reality Distraction on Patient's Anxiety Before Coronary Angiography

#### Protocol summary

##### Study aim

The Effect of Virtual Reality Distraction on Patient's Anxiety Before Coronary Angiography

##### Design

Two arm parallel group (intervention and control) randomized clinical trial, no blinded, daily simple random sampling method, sample size is 80 participants.

##### Settings and conduct

To create virtual reality in the intervention group, we will use a virtual reality headset, a mobile phone and headphones to play the sound. A video via a mobile phone will be played that can change the viewing angle of 360 degrees while changing the patient's head position. Its contents include relaxing landscapes such as nature, beach, sea, etc. The video will be played by mobile phone, before transporting the patient to the Cardiac Angiography Suite of Heshmat Educational Medical Center.

##### Participants/Inclusion and exclusion criteria

All patients aged 40 to 60 years old are candidates for angiography; No history of angiography; Lack of motion sickness; No severe audio and visual disability; Lack of psychiatric disease; Not wanting to continue the experimental sample; No symptoms of anxiety

##### Intervention groups

Intervention involves the implementation of virtual reality on mobile phone for intervention group. In the control group, virtual reality will not be implemented. The equivalent time playing virtual reality for the intervention group will be present in the control group. The researcher will be next to the participant and no action will be taken.

##### Main outcome variables

Heart rate; Respiratory rate; Blood pressure; Anxiety level

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20140515017693N3**  
Registration date: **2019-03-03, 1397/12/12**  
Registration timing: **prospective**

Last update: **2019-03-03, 1397/12/12**

Update count: **0**

##### Registration date

2019-03-03, 1397/12/12

##### Registrant information

##### Name

Mohammad Reza Yeganeh

##### Name of organization / entity

Guilan University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 13 1555 5056

##### Email address

yeganeh@gums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-03-06, 1397/12/15

##### Expected recruitment end date

2019-05-05, 1398/02/15

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The Effect of Virtual Reality Distraction on Patient's Anxiety Before Coronary Angiography

**Public title**  
Effect of Virtual Reality Distraction on Patient's Anxiety

**Purpose**  
Prevention

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
All patients aged 40 to 60 years old candidated for angiography  
**Exclusion criteria:**  
History of Angiography Motion Sickness Intense Hearing and Visual Disability Psychiatric Diseases

**Age**  
From **40 years** old to **60 years** old

**Gender**  
Both

**Phase**  
N/A

**Groups that have been masked**  
*No information*

**Sample size**  
Target sample size: **80**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
Sampling will be performed with daily simple random sampling method. First, on a piece of paper, the name of the "intervention group", and on an another one, the name of the "control group" will be written, and placed in a bowl. Then one of the colleagues who do not have a role in sampling will randomly draw a paper. Whatever the result, the first day of sampling will be assigned to that group; then the next day, the sampling will be assigned to the other group. In other words, in one day, samples of the intervention group, and the next day the control group will be collected. Each groups, which reach earlier to 40, sampling for the other group will continue in the same way at one-day intervals to complete the sampling process for that group.

**Blinding (investigator's opinion)**  
Not blinded

**Blinding description**

**Placebo**  
Not used

**Assignment**  
Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**  
**Name of ethics committee**  
Guilan University of Medical Sciences  
**Street address**  
Gillan - Rasht - Namjoo Street - opposite Azodi Stadium - Gilan University of Medical Sciences  
**City**

Rasht  
**Province**  
Guilan  
**Postal code**  
65385-41446

**Approval date**  
2018-12-31, 1397/10/10

**Ethics committee reference number**  
IR.GUMS.REC.1397.369

## Health conditions studied

### 1

**Description of health condition studied**  
Anxiety in candidates for coronary angiography  
**ICD-10 code**  
**ICD-10 code description**

## Primary outcomes

### 1

**Description**  
Anxiety Scale in Short Version of the Spielberger's Anxiety Measurement Scale  
**Timepoint**  
Measuring anxiety score before and after intervention  
**Method of measurement**  
Short Version of the Spielberger's Anxiety Measurement Scale

### 2

**Description**  
Systolic and diastolic blood pressure  
**Timepoint**  
Measuring systolic and diastolic blood pressure before and after intervention  
**Method of measurement**  
Aneroid sphygmomanometer

### 3

**Description**  
Heart rate in one minute  
**Timepoint**  
Counting heart rate in one minute before and after intervention  
**Method of measurement**  
A stopwatch of a digital watch

### 4

**Description**  
Respiratory rate in one minute  
**Timepoint**  
Counting respiratory rate in one minute  
**Method of measurement**  
A stopwatch of a digital watch

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: Intervention involves the implementation of virtual reality on mobile phone for intervention group. In the control group, virtual reality will not be implemented. To create virtual reality in the intervention group, we will use a virtual reality headset, a mobile phone and headphones to play the sound. A video via a mobile phone will be played that can change the viewing angle of 360 degrees while changing the patient's head position. Its contents include relaxing landscapes such as nature, beach, sea, etc. The video will be played by mobile phone, before transporting the patient to the Cardiac Angiography Suite. Sounds include soft music, birds singing and the sound of the waterfall. The duration of this video will be 5 minutes.

#### Category

Prevention

### 2

#### Description

Control group: In the control group, virtual reality will not be implemented. The equivalent time playing virtual reality for the intervention group will be present in the control group. The researcher will be next to the participant and no action will be taken.

#### Category

N/A

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Hospital Heart Dr Heshmat

##### Full name of responsible person

Mohammad Reza Yeganeh

##### Street address

15 Azar St, next to Management and Planning Organization

##### City

Rasht

##### Province

Guilan

##### Postal code

4193955588

##### Phone

+98 13 3366 9064

##### Fax

+98 13 3366 8718

##### Email

heshmat@gums.ac.ir

##### Web page address

<http://www.gums.ac.ir/heshmat>

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Rasht University of Medical Sciences

##### Full name of responsible person

Shadman Nemati

##### Street address

Opposite 17th Shahrivar Hospital, Shahid Siadati St., Namjou St.

##### City

Rasht

##### Province

Guilan

##### Postal code

4144666949

##### Phone

+98 13 3333 5821

##### Email

research@gums.ac.ir

#### Grant name

#### Grant code / Reference number

#### Is the source of funding the same sponsor organization/entity?

Yes

#### Title of funding source

Rasht University of Medical Sciences

#### Proportion provided by this source

100

#### Public or private sector

Public

#### Domestic or foreign origin

Domestic

#### Category of foreign source of funding

empty

#### Country of origin

#### Type of organization providing the funding

Academic

## Person responsible for general inquiries

#### Contact

##### Name of organization / entity

Rasht University of Medical Sciences

##### Full name of responsible person

Mohammad Reza Yeganeh

##### Position

Faculty member

##### Latest degree

Master

##### Other areas of specialty/work

Nursery

##### Street address

Nursing & Midwifery Faculty, Guilan University of Medical Sciences, Daneshjoo St., Shahid Beheshti A

##### City

Rasht

##### Province

Guilan  
**Postal code**  
416351873  
**Phone**  
+98 13 1555 5056  
**Fax**  
+98 13 1555 0097  
**Email**  
yeganeh@gums.ac.ir

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Rasht University of Medical Sciences  
**Full name of responsible person**  
Mohammad Reza Yeganeh  
**Position**  
Faculty member  
**Latest degree**  
Master  
**Other areas of specialty/work**  
Nursery  
**Street address**  
Nursing & Midwifery Faculty, Guilan University of  
Medical Sciences, Daneshjoo St., Shahid Beheshti  
Ave., Rasht  
**City**  
Rasht  
**Province**  
Guilan  
**Postal code**  
41469-39814  
**Phone**  
+98 13 1555 5056  
**Fax**  
**Email**  
yeganeh@gums.ac.ir  
**Web page address**

## Person responsible for updating data

### Contact

**Name of organization / entity**  
Rasht University of Medical Sciences  
**Full name of responsible person**  
Mohammad Reza Yeganeh  
**Position**  
Faculty member  
**Latest degree**  
Master  
**Other areas of specialty/work**  
Nursery  
**Street address**

Nursing & Midwifery Faculty, Guilan University of  
Medical Sciences, Daneshjoo St., Shahid Beheshti  
Ave., Rasht

**City**  
Rasht  
**Province**  
Guilan  
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**Email**  
yeganeh@gums.ac.ir  
**Web page address**

## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

### Study Protocol

Yes - There is a plan to make this available

### Statistical Analysis Plan

Yes - There is a plan to make this available

### Informed Consent Form

Yes - There is a plan to make this available

### Clinical Study Report

Yes - There is a plan to make this available

### Analytic Code

Not applicable

### Data Dictionary

Not applicable

### Title and more details about the data/document

The table of final results of the variables in data form and after statistical analysis is sharable without the individual information of each sample.

### When the data will become available and for how long

Reachable in 2019

### To whom data/document is available

Researchers and students in academic and scientific institutions, people working in the industry

### Under which criteria data/document could be used

A variety of statistical analyzes will be allowed on data.

### From where data/document is obtainable

Guilan University of medical Sciences, Vice chancellor for research Corresponding author: Mohammad Reza Yeganeh Address: Faculty of Nursing & Midwifery, Daneshjou St., Martyr Beheshti Boulevard, Rasht +981333555058 info@gums.ac.ir

### What processes are involved for a request to access data/document

After submitting the application, the application is examined at the research council and the individual can access the data for a maximum of two months.

### Comments